K062348

SEP - 8 2006

4. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number:	2021898
Address of Manufacturer:	Medtronic Neurosurgery 125 Cremona Drive Goleta CA, 93117 (805) 968-1546 ext. 1773 Fax: (805) 968-9336
Contact Person:	Jeffrey Henderson
Date:	August 3, 2006
Trade or Proprietary Name:	TiMesh® System
Common usual or Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (888.3030)
Predicate Device Identification:	TiMesh® System (K974017, K923419)

Description: The device consists of a system of mesh, wire, screws, and plates of various sizes and shapes to be used for rigid or semi-rigid internal fixation.

Intended Use: The TiMesh System is intended for use in any oral-maxillo-cranio-facial surgical reconstructive procedure, either orthognathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together. Alternatively, the TiMesh System is also indicated for use in reinforcing weak bony tissue in orthopaedic surgical procedures such as pelvic reconstruction, acetabular reconstruction, and cement restriction. This product is not intended for spinal use.

Intended Use of predicate device(s): The TiMesh System is intended for use in any oral-maxillo-cranio-facial surgical reconstructive procedure, either orthognathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together. Alternatively, the TiMesh System is also indicated for use in reinforcing weak bony tissue in orthopaedic surgical procedures such as pelvic reconstruction, acetabular reconstruction, and cement restriction. This product is not intended for spinal use.

Technological comparison: Medtronic Neurosurgery submits that the materials of fabrication, intended use, and the fundamental scientific technology of the TiMesh System is the same as the previously reviewed and cleared TiMesh System. Based upon the summary above, Medtronic Neurosurgery determines substantial equivalence, safety, and

efficacy of the TiMesh System products compared to the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 8 2012

Medtronic Neurosurgery
% Mr. Jeffrey Henderson
Vice President, Quality & Regulatory Affairs
125 Cremona Drive
Goleta, California 93117

Re: K062348
Trade/Device Name: TiMesh® System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 3, 2006
Received: August 16, 2006

Dear Mr. Henderson:

This letter corrects our substantially equivalent letter of September 8, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical

device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic & Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K062348

Device Name: TiMesh® System

Indications for Use:

The TiMesh System is intended for use in any oral-maxillo-cranio-facial surgical reconstructive procedure, either orthognathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together. Alternatively, the TiMesh System is also indicated for use in reinforcing weak bony tissues in orthopaedic surgical procedures such as pelvic reconstruction, acetabular reconstruction, and cement restriction. This product is not intended for spinal use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K062348 44

Page 1 of 1